The Remote Trauma Outcomes Research Network: Rationale and methodology for the study of prolonged out-of-hospital transport intervals on trauma patient outcome

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The time elapsed between injury and hemostasis is inversely proportional to survival and functional recovery in the trauma patient.[1,2] Yet, we remain largely naïve to the pathophysiologic sequence that unfolds during this critical time frame.[3,4] Likewise, prolonged evacuations encountered by critically wounded combatants may pose similar hazards. Little room for improvement remains in hospital-based care, however, when one considers the 97% survival rate for casualties engaged by the Joint Trauma System.[5] In contrast, the out-of-hospital and preoperative phase of care (referred to as NATO Role I) represent perhaps our greatest opportunity to further reduce combat death.[6,7]

Ironically, many of the greatest advances in medical and surgical practice have occurred as a consequence of armed conflict. The impending resolution of contemporary conflicts in Iraq and Afghanistan is a welcome development, but with it will come a "loss" of the opportunity to observe, learn, and innovate while engaged in combat casualty care. Thus, if advances are to continue, it will be necessary to refocus existing clinical investigation networks engaged in battlefield care research and to seek a relevant setting other than war to continue this vital effort.

The Remote Trauma Outcomes Research Network (Rem TORN) is the first and largest investigation to date of trauma patients undergoing prolonged preoperative treatment and transport. By providing a model complementary to the current deployed environment in terms of geospatial, temporal, and scope-of-practice characteristics, it may enable rigorous and relevant studies of out-of-hospital care, new diagnostic and therapeutic approaches, and their collective effect on outcomes. Ultimately, it may enable the establishment of remote damage-control resuscitation (RDCR) as a clinical practice.

Epidemiologically, trauma is the fourth leading cause of death in the United States and leads among people younger than 44 years.[8] Blunt mechanisms predominate, with subpopulations and geospatial sectors in which penetrating trauma has a higher prevalence.[9,10] This threat is amplified exponentially during armed conflict. While the modern battlefield has greater geospatial expanse, the primary wounding mechanisms and causes of death remain similar to past conflicts.[11,12] At least three phenomena contribute as follows: (1) advances in weapons technology, (2) asymmetric and unconventional warfare by our adversaries, and (3) limited success in assimilating emerging best practices in civilian and military emergency care.[13]

Mounting evidence corroborates the linkage between skilled tactical emergency care and improved casualty survival. In a study of conventional combat units in an urban warfare setting, Gerhardt et al.[14] reported a 35% decrease in mortality associated with skilled tactical emergency care, a hypotensive resuscitation strategy, and an emergency medical services (EMS) model for directing combat medics. Kotwal et al.[15] reported a 44% decrease in case fatality in the 75th Ranger Regiment, attributed to universal tactical combat casualty care training and command oversight. Most recently, Mabry et al.[16] reported a 47% decrement in 48-hour postinjury mortality in a retrospective study of advanced life support en route care versus the contemporary basic life support model used by Army MEDEVAC units before 2012.

Tremendous progress has been realized in preventing death from compressible extremity and junctional hemorrhage.[17,18] Nonetheless, more than 15% of contemporary casualties sustain torso trauma, and others sustain multiple punctures and lacerations from complex improvised weapons, rendering nonoperative hemorrhage control virtually impossible.[6]

Current options for treatment are severely limited.[19,20] Rapid access to surgery is the primary objective. Available data reveal an excess of 75% of combat fatalities occurring before arrival at a surgical facility.[6] Thus, our best opportunity to improve survival is to assure rapid and effective performance of required lifesaving interventions, followed by an optimized strategy to maintain satisfactory tissue perfusion while mitigating coagulopathy while en route to definitive care.[21]

Contemporary casualties often sustain multiple wounds from blasts or crashes, penetrating injuries from projectiles, and

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significant burns.[6] Many manifest uncontrolled major hemorrhage. Some progress to irreversible shock, coagulopathy, acidosis, and ultimately death.[22] Damage-control resuscitation (DCR) and damage-control surgery principles were exported to the contemporary battlefield to counteract this pathologic course.[23] Retrospective studies examining DCR demonstrate improved survival rates ranging from 16% to 40% compared with standard care in both combat and civilian settings.[24–26]

Practically speaking, to perform DCR, one requires a surgical team and a blood bank. With current and projected battlefield constraints, further DCR implementation will be limited by the supply of surgical teams, complex tactical medical evacuation chains, and an increasingly dispersed battle space, including a sea-based expeditionary strategy. In civilian settings, the trend toward regionalization of trauma systems and increasing demand for access by populations historically outside the range of existing trauma systems will generate similar obstacles. This begs the question: could we project DCR forward of the trauma center and initiate some components before the patient decompensates?

Anecdotal examples of success have been reported in combat and domestic trauma settings.[27] What remains is to conceptualize, develop, evaluate, and implement an strategy for RDCR within the constraints imposed by the prehospital environment.[21]

PATIENTS AND METHODS

Our primary hypothesis is that patients with uncontrolled major hemorrhage undergoing prolonged evacuation might benefit from RDCR before trauma center arrival.

RemTORN arose from collaboration among stakeholders in trauma and emergency care, the military, and public policy arenas. The following questions emerged from the dialogue:

1. What impact, if any, does preoperative stabilization and en route care have on patient outcome, particularly in remote settings?
2. Can we find ways to predict clinical deterioration before trauma center arrival?
3. If we began RDCR before trauma center arrival, could we improve survival?

RemTORN's first objective is to establish infrastructure to integrate field and multisite inpatient clinical record data for trauma patients undergoing initial stabilization at remotely located State of Texas–verified Level IV trauma centers (emergency resuscitative surgical capability is not routinely available) followed by transfer to one of the two existing American College of Surgeons/Texas–verified Level I trauma centers in San Antonio, all in collaboration with the Southwest Texas Regional Advisory Council for Trauma (STRAC) (Fig. 1). Observational studies of epidemiology, pathophysiology, and clinical outcome will then be inaugurated. Subsequently, RemTORN will progress to clinical trials to derive and validate clinical practice guidelines to enable RDCR implementation.

The participation of human subjects requires ethical and regulatory safeguards, which are as critical as they are complex. This is amplified in the out-of-hospital arena. While RemTORN will eventually conduct clinical trials, it will be inaugurated with observational studies that pose no more than minimal risk. When possible, we will establish evidence-based regional guidelines for evaluation by process improvement methods. Currently approved methods and adjuncts may be leveraged to enable investigations of new or modified approaches to care. Clinical trials will be initiated modestly then built upon progressively, relying heavily on community involvement and consensus.

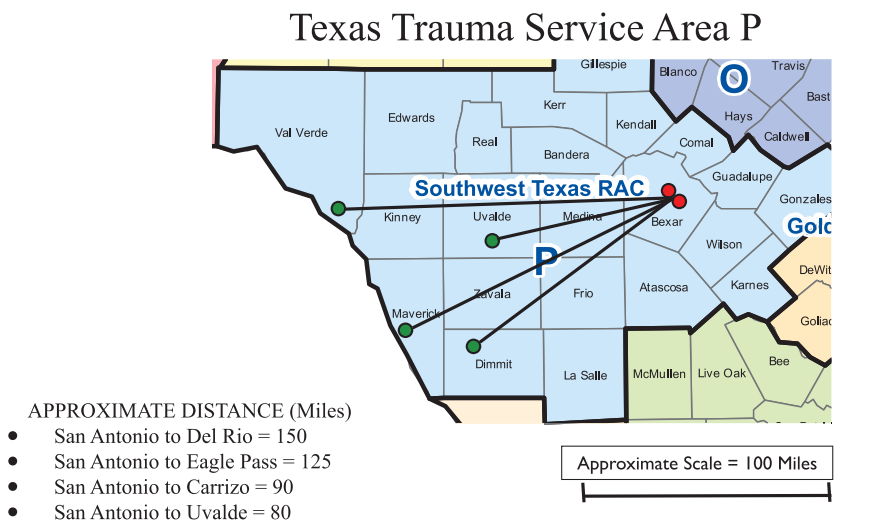
RemTORN's study design begins as an observational cohort of trauma patients from selected Texas Level IV verified trauma centers participating in the network, who subsequently undergo interfacility transport to the Brooke Army Medical Center or University Health System trauma centers in San Antonio.

RemTORN Phase I focuses on establishment of the Rem TORN trauma registry staff, infrastructure, information technology components, software, security and data integrity safeguards, field data collection, trauma registry support at Level IV facilities, and retrospective population of the registry. Analysis of this registry will establish baseline metrics and permit validation of the model and procedures.

RemTORN Phase II will incorporate observational studies of novel physiologic monitors designed to estimate central blood volume and to predict onset of shock. Coincidental to their trauma care, all RemTORN subjects receive standard noninvasive monitoring. As a natural consequence, arterial wave forms are generated by transcutaneous pulse oximeters. While Food and Drug Administration–approved for use, these devices possess additional potential if their aforementioned wave forms are unmasked.[28] This enables further study using novel hemodynamic signal processing algorithms.[28] Several of these algorithms have shown promise in a lower-body negative-pressure model of progressive central hypovolemia in healthy human volunteers but require validation in actual patients with coexisting comorbid states.[29]

Phase II will be accomplished by recording continuous arterial pulse wave form data during the balance of treatment

Figure 1. Afghanistan contemporary operational area.



Courtesy Texas Department of State Health Services http://www.dshs.state.tx.us/emstraumasystems/etrauma.shtm

Figure 2. Texas Trauma Service Area P.

at the initiating facility, during interfacility transport, and at the receiving trauma center, followed by retrospective recovery and analysis. The end point will be arrival either in the operating room, intensive care unit, downgrade of the subject's status if stable, or death.

Monitor data will be analyzed retrospectively using the experimental hemodynamic signal processing algorithm. Corresponding clinical data will be obtained from the RemTORN registry and correlated in a manner not unlike the reconciliation of continuous cardiac event monitoring with clinical logs. RemTORN Phase II will seek to determine whether the algorithm will perform similarly in adult trauma patients experiencing ongoing hemorrhage during their preoperative phase of care.

The primary outcome of interest in this phase will be the degree of correlation between the noninvasive hemodynamic monitor coupled with the experimental hemodynamic signal processing algorithm and clinical events as they unfold. In such cases, the earliest time point in which the algorithm predicts imminent cardiovascular collapse will be compared with actual event and intervention times based on changes in standard vital signs (the current standard of care) and clinical records. Based on previous process improvement studies, we estimate that 20% of our projected sample population will develop hemodynamic instability before arrival at definitive care. With a matching set of stable transfer subjects and presuming an α error of less than 5% and a power of 80%, we project the ability to detect a difference in accuracy (contingency table method with continuity correction) of 17%; for example, that would translate to identification of a significant difference in accuracy of 80% for the hemodynamic signal processing algorithm compared with 63% for standard vital signs. Likewise, if we wish to assess the time difference between initiation of monitoring and onset of hemodynamic decompensation, we would be able to detect a significant difference of 3.7 minutes.

RemTORN Phase III adds the collection of serial blood samples for determining thromboelastometry data. Collection will occur as part of routine trauma panels drawn at RemTORN Level IV facilities, followed by a second sample obtained upon arrival at the Level I trauma centers. Subsequently, these data will be used to analyze trends relating onset and progression of coagulopathy as a function of elapsed time from initial treatment to definitive hemostasis. With this approach, Phase III holds the promise of defining both when and under which circumstances acute traumatic coagulopathy develops.

The primary outcomes of interest for this phase are thromboelastometry data (APTEM, EXTEM, and FIBTEM, TEM Systems, Durham, NC), prothrombin time, and international normalized ratio (INR) as markers for acute traumatic coagulopathy. Presuming that the primary cause of clinical decompensation is hemorrhage, we estimate a potential sample size of 100 patients who will decompensate before Level I trauma center arrival during the 2-year period of data collection, which we project to be available after regulatory approval and platform establishment. With a matching set of 100 nonhemorrhaging subjects from our total sample population and presuming an α error of less than 5% and a power of 80%, we project the ability to detect a difference in INR of 0.4 between hemorrhaging patients and those who have had effective hemostasis, given a standard deviation of 1. Rationale behind this benchmark rises from previous studies identifying an INR greater than 1.5 as predictive of coagulopathy and transfusion requirement.

SAMPLE POPULATION

Our objective was to enroll all eligible patients as they accumulate. Based on referral patterns and transfer records, we estimate 36 interfacility trauma transfers generated per month.

Specific inclusion criteria are age of 18 years to 80 years, accepted for trauma transfer to participating Level I trauma centers, successful interfacility transfer, or death en route. Exclusion criteria are voluntary post hoc subject withdrawal and incomplete data sets.

SETTING

The South Texas Border Region is predominantly rural, with a widely dispersed population. It is served by a series of community hospitals, none possessing routine acute care surgical capability, although equipped with 24-hour emergency services.[30] These facilities habitually refer patients requiring trauma center care exclusively to San Antonio Military Medical Center or University Health System, with the preponderance transported by the San Antonio AirLIFE air medical transport program. The time and distance variables for the selected facilities include a range of 75 nautical miles to 150 nautical miles and time intervals before Level I trauma center arrival ranging from 40 minutes to an excess of 6 hours. These characteristics reflect typical transport time and distance characteristics experienced currently by the US and Coalition forces in the Middle East. STRAC, which corresponds geographically to Texas Trauma Service Area "P," represents a robust and mature network of community hospitals, regional trauma centers, EMS units, and research institutes.[30]

TECHNICAL RISKS

In our design, we have sought to avoid or mitigate obstacles by using strategies proven effective in similar out-of-hospital research initiatives. These include (1) leveraging existing passive data collection mechanisms; (2) limiting initial studies to minimal-risk observational designs, which facilitate subject enrollment and are intended to qualify for waiver of informed consent; and (3) using redundancy by incorporating multiple initial treatment facilities and two trauma centers, to optimize power and mitigate error.

DATA MANAGEMENT

STRAC Clinical Informatics Division will serve as the data management facility for the RemTORN project. It collects and aggregates data from both primary and secondary sources. All use the same registry software program (Collector, Digital Innovations, 2011). This registry currently contains approximately 75,000 records and annually adds approximately 10,000 records.

The second primary data source is an out-of-hospital registry, capitalizing on regional deployment of an electronic health record (Tablet PCR), currently in use by 28 of our 31 EMS agencies throughout the region. This application generates National Emergency Medical Services Information System (NEMSIS)-compliant records. This database recently passed the milestone of 1,000,000 entries, with roughly 200,000 added annually.[31]

TIMELINE

Retrospective reviews have been conducted to project sample size, examine basic demographics and epidemiology for goodness of fit, and enable construction of the integrated registry. RemTORN Phase I is scheduled to begin formally in the early summer of 2012. Phase II is projected to commence in summer 2013, followed by Phase III trials in winter 2013.

AUTHORSHIP

R.T.G. conceptualized the network, performed the literature search, designed the study, analyzed and interpreted the pilot data, and wrote the manuscript. D.G.B. assisted with the manuscript writing and performed critical revisions. A.P.C. assisted with the interpretation of pilot data, assisted with the manuscript writing, and performed critical revisions. R.C. assisted with the manuscript writing and performed critical revisions. M.A.D. assisted with the manuscript writing and performed critical revisions. J.H. assisted with the literature search, interpretation, and manuscript writing and performed critical revisions. A.R.K. assisted with the literature search and manuscript writing. J.L. assisted with the manuscript writing and critical revisions. A.R.M. assisted with the study design, analysis, and critical revisions. C.M. assisted with the manuscript writing and critical revisions. R.S. assisted with the study design and manuscript writing. T.E.R. assisted with the interpretation and critical revisions. F.K.B. assisted with the manuscript writing. V.C. assisted with critical revisions. L.H.B. assisted with the design, manuscript writing, and critical revisions

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DISCLOSURE

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EDITORIAL CRITIQUE

In this issue of the *Journal of Trauma and Acute Care Surgery*, Gerhardt et al. report on a military-civilian partnership spanning 26,000 sq mi of southwest Texas. In the Remote Trauma Outcomes Research Network (RemTORN) articles, the authors compare injury characteristics and evacuations distances and times in civilian Trauma Service Area-P to those encountered by the military in Afghanistan. This collaboration, referred to as "the Del Rio Model" more than a decade ago, formed the basis for the military's Joint Trauma System or JTS in 2004. The current work by these authors represents a maturing of this collaboration and confirms what was recognized by those who initiated the JTS, specifically, that a number of important similarities exist between the medical evacuation patterns in Trauma Service Area-P and those required by the military in the movement of injured troops.

Differences in demographics and injury characteristics between civilian patients in Trauma Service Area-P and those injured in the battlefield are a given. However, these differences are less important than the demonstration by these authors that this unique military-civilian research collaboration works. The Del Rio Model serves as a platform on which the military can work with civilian institutions to study data recording tools, monitoring devices, and resuscitation techniques in an interwar period. Not to be overlooked is the effect on trauma care in this civilian sector, which stands to benefit from the military's extensive experience and investment in the prehospital setting.

While not completely unique among civilian trauma networks across the United States, Trauma Service Area-P is singular in its integration with the military's Level I trauma center and Institute of Surgical Research at Joint Base Fort Sam Houston in San Antonio. As the pace of combat operations decreases in Afghanistan, it will be essential for all levels of civilian trauma to collaborate smartly with the military's combat casualty care research program. In the context of the RemTORN project, these collaborations stand to maintain the military's capacity to garner experience from and perform investigation in the prehospital arena. May we continue to build upon the superb example and foundation provided by these dedicated investigators.

*The author declares no conflict of interest.

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